Electronic Establishment Registration and Product Listing Update: FURLS - TRLM

FURLS = FDA Unified Registration and Listing System

TRLM = Tobacco Registration and Product Listing Module

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Center for Tobacco Products
U.S. Food and Drug Administration

Topics Covered

- Brief overview of establishment and product listing requirements
- What is the FDA Unified Registration and Listing System (FURLS)?
- Benefits of using FURLS
- Tips for using FURLS
- Resources if you need help

Establishment Registration and Product Listing Requirements

- Annual registration
 - On or before December 31st of each year
- Biannual product listing updates (if changes have been made)
 - June and December

Additional Resources

- Section 905 of the Federal Food, Drug, and Cosmetic Act
- Guidance for Industry is available at www.fda.gov by searching for "Tobacco Registration and Listing Guidance"
- CTP held a webinar on December 8, 2011, which is also available at www.fda.gov by searching for "2011 Archived Tobacco Compliance Training"

What is FURLS TRLM?

- FURLS is the FDA Unified Registration and Listing System
- FURLS is also used by other Centers within FDA
- TRLM is the new Tobacco Registration and Product Listing Module of FURLS

Why did CTP Transition from eSubmitter to FURLS?

- FURLS is a more user-friendly, online system
- FURLS allows firms to view and edit their data at any time
- Note that establishment registration and product listing is the <u>only</u> submission type transitioning from eSubmitter to FURLS

Additional Benefits of FURLS

- You do not have to download an additional program to your computer
- You no longer need to "package" files and use a separate system (ESG) to submit
- You can re-use the same spreadsheet that was used to upload product listings in eSubmitter

What Happened to Data Submitted through eSubmitter?

- CTP has migrated all current establishment registration and product listing data into FURLS
- Accounts were created for firms with existing registration and product listing data
- If you did not receive your account information, contact CTPRegList@fda.hhs.gov

Can I Still Use the Paper Form?

- Yes, paper form FDA 3741 is still available for submitting establishment registration and product listing information
- However, CTP strongly encourages you to view and edit your data online using FURLS

Do I Have to Submit Any New or Different Information?

- No you will provide the same establishment registration and product listing information
- The form questions have not changed; only the electronic method for submitting this information has changed

Adding Advertising, Labeling, and Consumer Information

 The system accepts the following file types: .pdf, .xpt, .xml, .dtd, .gif, .tif, .jpg, .sgml, .mol, .xls, .xlsx, .csv, .wmv, .avi, and .zip

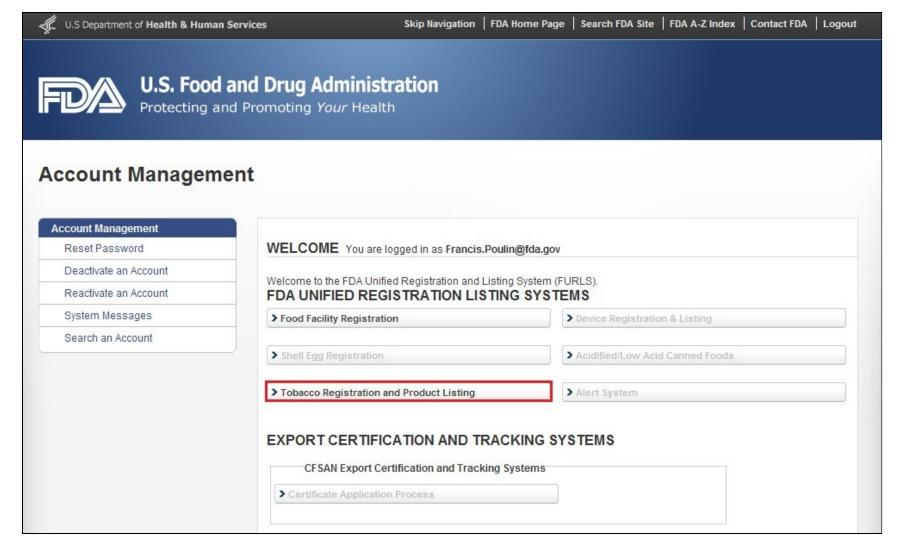
FURLS Streamlines the Submission of Information

For example:

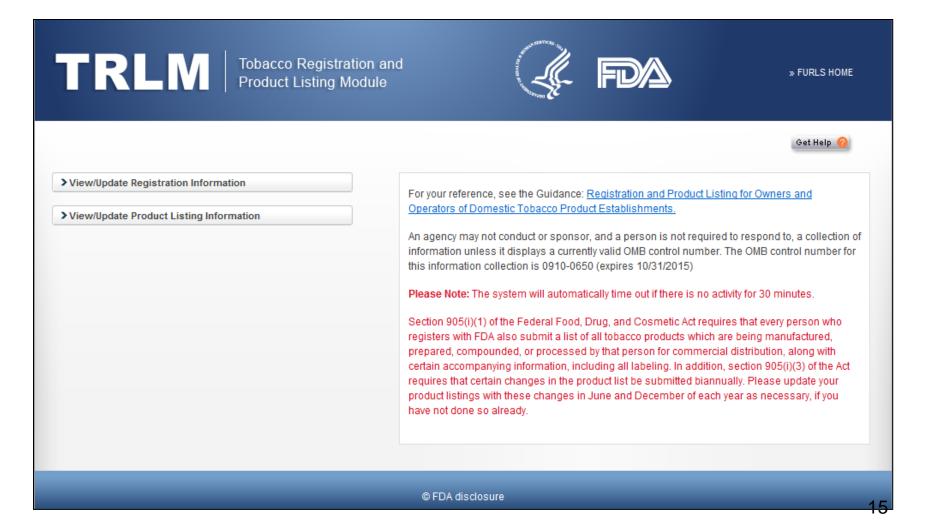
- If there are no changes to your establishment registration, you can now simply check a box
- If there is no advertising, labeling, or consumer information for a product, you can indicate this by checking a box
- If you have multiple establishments, you can indicate where listed products are made

Tips for Using FURLS

Logging into FURLS



View/Update Existing Data



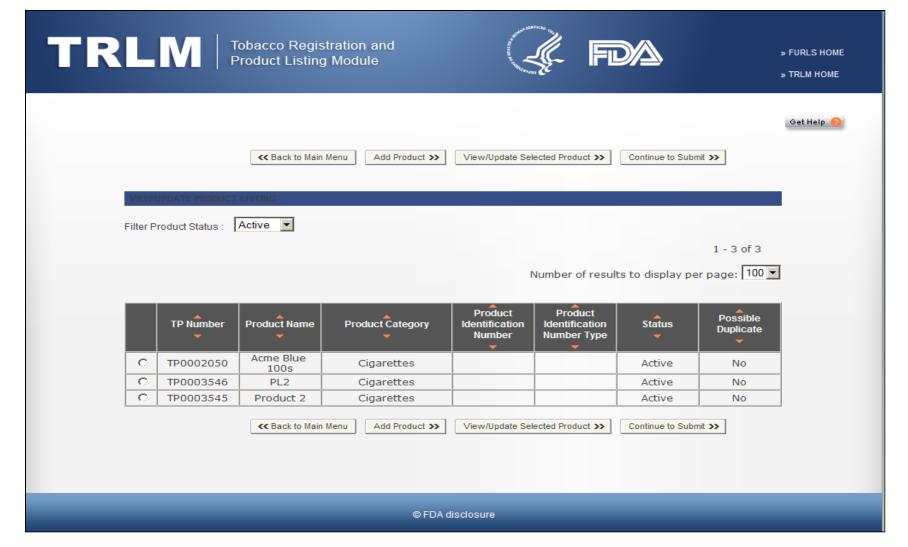
Owner who is also the Operator



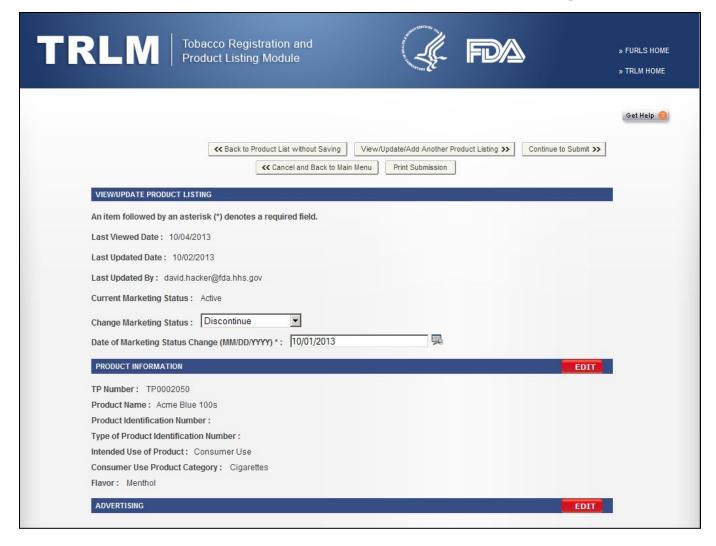
Annual Registration



View/Update Product Listings



View/Update Product Listings (cont)



Where to Get Help

- While logged into FURLS, you can click the "Get Help" icon in the upper right hand corner of each screen for a step-by-step tutorial:
- You can send an email to <u>AskCTP@fda.hhs.gov</u>; please include your FURLS account ID
- Small manufacturers can contact <u>smallbiz.tobacco@fda.hhs.gov</u>; please include your FURLS account ID
- CTP will have staff available to assist you with your questions